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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,973	03/01/2002	Kesavan Esuvaranathan	488002000200	6742

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EXAMINER	
SCHNIZER, RICHARD A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 03/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/086,973	ESUVARANATHAN ET AL.	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-16,18-31,33,34,36-41,43,44,46-57 and 59-64* is/are pending in the application.

4a) Of the above claim(s) *1,3-16,18-31,33,34,36-41,43,44,46-56 and 62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *57, 59-61, 63, and 64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

An amendment was received and entered on 12/22/04.

Claims 2, 17, 32, 35, 42, 45, and 58 were canceled.

Applicant's election without traverse of group 25 and the species of cationic lipids is acknowledged. Claims 1, 3-16, 18-31, 33, 34, 36-41, 43, 44, 46-56 and 62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/22/04.

Note that claim 63 recites a Markush group comprising non-elected species, i.e. PAMAM, polylysine, polyhistidine, polyarginine, polyethyleneimine, poly(4vinylpyridine), poly(vinylamine), poly(4-vinyl-N-alkyl pyridinium halide), and combinations comprising these. Claim 63 will be considered only to the extent that it reads on the elected species of cationic lipids.

Claims 1, 3-16, 18-31, 33, 34, 36-41, 43, 44, 46-57, and 59-64 are pending in the application.

Claims 57, 59-61, 63, and 64 under consideration in this Office Action.

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence(s) of the specification or in an application data sheet by identifying the prior application by application number (37 CFR 1.78(a)(2) and (a)(5)). **If the prior application is a non-**

provisional application, the specific reference must also include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. The instant specification fails to indicate the relationship between itself and PCT/SG00/00130. Appropriate correction is required.

Also, no certified copy of the priority document PQ 2593 is of record in the application. A certified copy of this document is required as per 35 USC 365(c). Due to the availability of intervening art, a translation of the priority document, if it is not in English, is also required.

Because the specification fails to indicate the relationship between itself and PCT/SG00/00130, the effective filing date of the instant application is 3/1/02.

Claim Objections

Claims 63 is objected to because it contains acronyms. Applicant should amend the first claim containing a given acronym to contain the full name of what is implied by the acronym. For example, claim "DOPE" should be deleted and replaced with dioleoylphosphatidylethanolamine (DOPE).

Compliance with Sequence Rules

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37

CFR 1.821 through 1.825 for the following reason(s). This application clearly fails to comply with the requirements of 37 C.F.R.1.821-1.825. Applicant's attention is directed to the final rule making notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998). **The specification at page 26, discloses oligonucleotides in excess of 9 bases that are labeled SEQ ID NOS: 1-4. However, there is no computer readable form or PAPER copy of a Sequence Listing of record in the application** Applicant must provide:

An initial computer readable form (CRF) copy of the "Sequence Listing".

An initial paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 57 and 59-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Lawrencia et al (Conference Supplement to Cancer Gene Therapy, Gene Therapy of Cancer VII, 12/1999), as evidenced by Lawrencia et al (Gene Therapy (8: 760-768, 2001).

Lawrencia (1999) taught a composition comprising DNA and DMBC. DMBC was defined as the cationic lipid DOTAP, and "two additives". Lawrencia (2001) disclosed that DMBC is DOTAP + methyl-beta-cyclodextrin solubilized cholesterol. Absent evidence to the contrary the DMBC of Lawrencia (1999) is the same as the DMBC of Lawrencia (2001). See abstract. So, Lawrencia (1999) taught a polynucleotide, DOTAP and methyl-beta-cyclodextrin solubilized cholesterol.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 57 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawrencia et al (Conference Supplement to Cancer Gene Therapy, Gene Therapy of Cancer VII, 12/1999) in view of Woodle et al (US 20030166601, published 9/4/03).

Lawrencia (1999) taught a composition comprising DNA, DOTAP, and methyl-beta-cyclodextrin solubilized cholesterol as discussed above.

Lawrencia did not teach the cationic lipids DOTMA, DOGS, DODAB, DODAC, DOSPA, DC-Chol, or DOPC.

Woodle taught that DOTAP, DOTMA, DOGS, DODAB, DODAC, DOSPA, DC-Chol, and DOPC were cationic lipids that were interchangeable in nucleic acid delivery compositions. See paragraphs 20, 97, 98, and claim 16. MPEP 2144.06 indicates that when it is recognized in the art that elements of an invention can be substituted, one for the other, while retaining essential function, such elements are art-recognized equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. In re Fout, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute any of the cationic lipids of Woodle for DOTAP in the nucleic acid delivery composition of Lawrencia.

Claims 57, 64, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Felgner et al (US Patent 5580859, issued 3/18/94) in view of Lawrencia et al (Conference Supplement to Cancer Gene Therapy, Gene Therapy of Cancer VII, 12/1999).

Felgner taught compositions comprising DOTAP and plasmid DNA, antisense oligonucleotides, phosphorothioate oligonucleotides, RNA molecules and ribozymes for transfection of bladder cells. See abstract, detailed description paragraphs 2, 55, and 126.

Felgner did not teach a composition comprising cyclodextrin solubilized cholesterol.

Lawrencia (1999) taught a composition comprising DNA, DOTAP, and methyl-beta-cyclodextrin solubilized cholesterol as discussed above for transfection of bladder cells.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the composition of Lawrencia to deliver the nucleic acids of Felgner to bladder cells. One would have been motivated to do so because Lawrencia taught that DOTAP combined with beta-cyclodextrin solubilized cholesterol is an effective agent for transfection of urothelial cells in vivo or in vitro. See conclusion.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, John Leguyader, be reached at 571-272-0760. The official central fax number is 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Richard Schnizer, Ph.D.